

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Clinical investigation of the safety and effectiveness of Excilia Hair strengthening and ani hair loss Lotion in improving male pattern androgenic hair loss

Protocol summary

Study aim

Clinical investigation of the safety and effectiveness of Excilia Hair strengthening and ani hair loss Lotion in improving male pattern androgenic hair loss

Design

Single group, phase 2, before -after clinical study.
sample size is 25. The study is not randomized.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 25 healthy volunteers will be selected and enrolled in the study after signing consent form. Volunteers are taught to use Topically use of Excilia Hair strengthening and anti-hair loss lotion for 24 weeks. Before intervention, 8,16,24 and 32 weeks after the start of use changing in hair lost will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male aged 18-55 years General health Hair Loss Status II, III, IV Based on Norwood Scale Voluntary participation and signing written informed consent Exclusion criteria: Chronic active scalp disease other than hair loss Using any prescribed drug or OTC for hair loss within the past 3 months Documented sensitivity to formulation components Any severe weight loss or strict diet therapy during the study Oral or topical treatment of minoxidil within 6 months before entering the study.

Intervention groups

Topically use of Excilia Hair strengthening and anti-hair loss lotion; Includes: Minoxidil oxathiazolidine carboxylate 5%, glycolic acid (AHA), caffeine, etc. for 24 weeks.

Main outcome variables

Count changes in terminal hair

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210130050179N6**

Registration date: **2023-02-12, 1401/11/23**

Registration timing: **prospective**

Last update: **2023-02-12, 1401/11/23**

Update count: **0**

Registration date

2023-02-12, 1401/11/23

Registrant information

Name

Taraneh Yazdanparast

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

drtaraneh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical investigation of the safety and effectiveness of Excilia Hair strengthening and ani hair loss Lotion in improving male pattern androgenic hair loss

Public title

Clinical investigation of the safety and effectiveness of Excilia Hair strengthening and ani hair loss Lotion in improving hair loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male aged 18-55 years General health Hair Loss Status II, III, IV Based on Norwood Scale Voluntary participation and signing written informed consent

Exclusion criteria:

Chronic active scalp disease other than hair loss Using any prescribed drug or OTC for hair loss within the past 3 months Documented sensitivity to formulation components Any severe weight loss or strict diet therapy during the study Oral or topical treatment of minoxidil within 6 months before entering the study.

Age

From **18 years** old to **55 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of The Institute of Pharmaceutical Sciences of Tehran University of Medical Science

Street address

Unit 1-219, 2nd floor, The Institute of Pharmaceutical Sciences, Faculty of Pharmacy, 16 Azar Avenue

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2023-01-30, 1401/11/10

Ethics committee reference number

IR.TUMS.TIPS.REC.1401.105

Health conditions studied

1

Description of health condition studied

Hair loss

ICD-10 code

L65.9

ICD-10 code description

Nonscarring hair loss, unspecified

Primary outcomes

1

Description

Count changes in terminal hair

Timepoint

Before intervention, 8, 16, 24 and 32 weeks after the start of use

Method of measurement

Trichoscopy By Fotofinder device

Secondary outcomes

1

Description

Hair count changes

Timepoint

Before intervention, 8, 16 and 32 weeks after the start of use

Method of measurement

Trichoscopy By Fotofinder device

2

Description

Hair lost Changes, based on Global photographic review

Timepoint

Before intervention, 8, 16 and 32 weeks after the start of use

Method of measurement

One independent dermatologist will perform clinical assessments in a blinded fashion by scoring every photograph according to the "Global photographic review" scale.

Intervention groups

1

Description

Intervention group: Topically use of Excilia Hair strengthening and anti-hair loss lotion; Includes: Minoxidil oxathiazolidine carboxylate 5%, glycolic acid (AHA), caffeine, etc. for 24 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for research and training in skin diseases and leprosy

Full name of responsible person

Aniseh Samadi

Street address

No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

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Province

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1416613675

Phone

+98 21 8897 0658

Email

dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zist orchid pharmed Company

Full name of responsible person

Araz Sabzevari

Street address

No 42, Atar street, Boostan alley, Kavosieh Ave

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Postal code

1994766411

Phone

+98 21 4347 3000

Email

ask@orchidpharmed.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zist orchid pharmed Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Taraneh Yazdanparast

Position

Research Physician

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

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No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

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drtaraneh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Position

Professor of dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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firozali@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable